Representative Erika Geiss
Testimony before the House Standing Committee on Health Policy for HB 4206 & HB 4691
Tuesday, September 29, 2015

Thank you, Chairman Callton and esteemed colleagues of the House Standing Committee on Health Policy for allowing me to testify this morning on House Bills 4206 and 4691—legislation that addresses the safety and distribution of human breast milk in the state of Michigan. I am particularly thrilled to be able to bring these two bills before the committee during Infant Mortality Awareness Month.

I also have with me here this morning, Cindy Duff from the Mothers Milk Bank at Bronson Methodist Hospital in Kalamazoo also representing the member milk banks of the Human Milk Banking Association of North America and Kendra Rowser from the Black Mother's Breast Feeding Association, each of whom will provide additional relevant testimony on the bills, their need and impact.

First, House Bill 4206 is a bill that would establish Michigan standards for collecting, preparing, storing and providing human breast milk for infant consumption by both non-profit human milk banks and for-profit human milk banking companies.

I'm sure you may be wondering why this issue is important enough to merit legislation. It is of critical importance for four key reasons:

Reason 1: It directly addresses the significantly high infant mortality rate in Michigan. Roughly seven infants die per 1,000 live births in our state, compared to about six per 1,000 nationally. In urban centers, the rate is much worse. Cities such as Battle Creek, Dearborn, Detroit, Flint, Grand Rapids, Lansing, Pontiac, Muskegon and Saginaw have infant mortality rates significantly higher than Michigan's. This issue however, is not limited to urban areas, and affects our entire state—urban, suburban and rural. Consider that the counties of Genesee, Kalamazoo, Kalkaska, Muskegon, Otsego and Wayne have an infant mortality rate of 10 per 1,000 live births or higher—which is higher than Michigan's infant mortality rate; the counties of Arenec and Presque Isle are at 15.0 per 1,000 live births—more than double Michigan's infant mortality rate.

Significantly, those numbers are also more than double the U.S. infant mortality rate of 6.1 per 1,000 live births (for 2014 according to U.S. Centers for Disease Control's and Central Intelligence Agency's most-recent data[i]), three times the rate of the United Kingdom, Germany and Spain, more than four times the infant mortality rate of the Netherlands and seven times that of Japan. The infant mortality rates for these regions of Michigan are also higher than a significant number of non-industrialized and newly industrialized nations—Armenia, Columbia, Libya, Malaysia, Peru and Uruguay, to name a few.

The positive impact of breastfeeding on lowering the risk of death from infectious diseases in the first two years of life is now well-established by the World Health Organization (WHO), Centers for Disease Control (CDC) and American Academy of Pediatrics (AAP) and has led to improvements in infant health and reductions in the infant mortality of the aforementioned and other developing nations. We should not expect any less for infants in Michigan.

Human breast milk is particularly important to premature infants facing necrotizing enterocolitis (or NEC)—a dire gastrointestinal complication that afflicts many premature infants and is a leading cause of death in this age group. Studies by the American Academy of Pediatrics[ii] and others have concluded the significant benefits of human breast milk in outcomes of infants with NEC. According to a 2012 study in the journal *Advanced Neonatal Care*:

> Necrotizing enterocolitis (NEC) is the most common and frequently dangerous gastrointestinal emergency in premature infants in the neonatal intensive care unit (NICU).[1] Although 90% of infants who develop NEC are born premature, full-term and near-term infants also develop the disease.[2] Modern technology and advances in clinical care have improved our ability to sustain and support infants born prematurely, but the prevalence of NEC has not decreased.[2,3] It is estimated that nearly 12% of infants born weighing less than 1,500 g will develop NEC; of those, about 30% will not survive.[2,3][iii]

Working to reduce these numbers is critical. And while premature birth often stems from a variety of issues from poor prenatal care, access to care, overall maternal health, gestational health and other issues, addressing and improving outcomes of neonates where possible is critical to lowering our infant mortality rate.

Reason 2: House Bill 4206 will improve the overall health outcomes of these fragile premature infants. The American Academy of Pediatrics, the Centers for Disease Control and the World Health Organization concur about the benefits of nursing/providing infants with human milk for a minimum of the first six months of life. In its 2012 *Executive Summary*, the AAP stated:

> Feeding preterm infants human milk has several significant short- and long- term beneficial effects. Lower rates of sepsis and necrotizing enterocolitis (NEC) indicate that human milk contributes to the development of the preterm infant's immature host defense. The incidence of NEC is significantly reduced (anywhere from 58% to 83%) with the feeding of human milk (even when fortified). However, preterm infants fed an exclusive human milk diet compared with those fed human milk supplemented with cow milk–based infant formula products had a 77% reduction in NEC and NEC surgery. Clinical feeding tolerance in preterm infants also is improved, and the attainment of full enteral feeding is hastened by a diet of human milk.[iv]

A mounting body of evidence continues to suggest many short-term and long-term benefits for infants who are breast-fed, benefits that also extend to infants nourished with safely procured human milk from donor or provider mothers.

For example, an even more-recent study from this year in the journal *Mucosal Immunology*, but not widely available until spring 2016 demonstrated that "Breast milk is the most effective strategy to protect infants against necrotizing enterocolitis (NEC)... [and found a] protective role for breast milk in NEC, and support a link between growth factor and innate immune receptors in NEC pathogenesis.[v]" And even in its 2012 Executive Summary statement, the American Academy of Pediatrics asserted that:

> The benefits of feeding human milk to preterm infants are realized not only [*in*] the NICU, but also in the fewer hospital readmissions for illness in the three years after hospital discharge. The potent benefits of human milk are such that all preterm infants should receive human milk. Milk from the infant's own mother, fresh or previously frozen, should be the primary diet, and it should be fortified appropriately for the infant born weighing less than 1.5 kg. If the mother's milk is unavailable despite significant lactation support, pasteurized donor milk should be used.[vi]

Reason 3: Given the improved health benefits of infants nourished with a diet of human milk, another clear benefit of using donor/provider milk in the NICU setting is a reduction in the cost of both short-term and long-term medical care. Also from the 2012 study in *Advanced Neonatal Care* cited earlier:

> The economic cost of NEC is high, accounting for approximately 19% of neonatal expenditures and an estimated $5 billion per year for hospitalizations in the United States alone.[9] If the disease can be managed medically, the cost of hospitalization has been estimated at around $73,700 with a length of stay exceeding on average 22 days more than that for other premature infants. However, if surgical care is required, there is at least an additional cost of $186,200, and [these] infants [tend to] stay [in-hospital for] an additional 60 days longer than other preterm infants.[vii]

Further, another study from the journal *Breastfeeding Medicine* found that there is "a direct net savings of $8,167 per [premature] infant [with NEC] receiving an exclusively human milk-based feeding strategy."[viii]

Reason 4: House Bill 4206 directly addresses the Surgeon General's 2011 *Call to Action to Support Breastfeeding*[x] in which 20 critical action items were outlined. This bill addresses specifically, Action 12—identify and address obstacles to greater availability of safe banked donor milk for fragile infants.

Any measures that we can take to improve neonatal outcomes and prevent or reduce infant mortality in Michigan, are significant ones.

In summary, House Bill 4206 seeks to:

- Set comparable standards for both non-profit human milk banks and for-profit human milk banking companies in Michigan
- Ensure that milk is collected ethically, protecting both the donor or provider mothers and their own infants
- Have any milk bank or milk banking company follow an established standard of protocols to ensure that the milk is collected safely (screened and free of pathogens and other substances harmful to infants), pasteurized or put through other safe and tested process
- Improve safe access to human milk especially for fragile infants thereby lowering risk for premature infant death and improving neonatal outcomes and reducing the infant mortality rate
- Create a mechanism where those involved in the various aspects of human lactation are working together for positive outcomes for maternal health, infant health and community health

Because traditional non-profit milk banks already have a rigorous set of guidelines, standards and measures that they employ at every step of their processes from collecting from donors through disseminating milk to infant patients, an additional set of standards are required for for-profit milk-banking companies to ensure that *any* company that wishes to engage in providing human milk for infant consumption is doing so within the same guidelines, practices and standards so that we do not have a "wild, wild West" of a milk banking industry that could adversely affect and create dire unintended consequences for our most fragile residents. The existing established for-profit milk banking companies in fact, already follow many of the "best-practices" outlined in the bill.

Today, there is a new frontier of a milk banking industry—and as the industry grows, it's important to make sure that milk banking in Michigan remains safe, all players are operating by the same standards, tenets and guidelines, and that our infants and donor or provider mothers remain protected. Women are the sole source of human milk and it is in the public interest to create mechanisms to equitably share the responsibility for this critical biological resource across all members of the population.

Women need information to make well-informed choices that reflect their goals and values when they consider donating or selling their milk and can work with hospital-based and community-based lactation consultants, their own physicians and children's pediatricians to make sound decisions that are best for their circumstances. Unlike donating blood, plasma or platelets, in most cases, milk donation is not an autonomous decision—the mother decides to donate or be a paid provider of milk only when she has enough to meet the needs of her children. Further, as the demand for human milk grows, the potential exists for economically disadvantaged women to be exploited for their milk by some companies and by other humans in their lives—it is critical that we take steps to reduce the chances for their exploitation and help keep mothers and their infants safe.

On that note, related to House Bill 4206 is **House Bill 4691**, which would amend the Michigan Food Law to prohibit the sale of human milk over the Internet in order to further ensure the safety of sold expressed human breast milk. A 2013 study of human breast milk sold over the Internet (on Internet classified sites other sites designed to facilitate or broker direct milk selling) 74% contained Staphylococcus, Streptococcus, Salmonella and other bacterium[x]. Another follow-up study published[xi] in Spring 2015 demonstrated that roughly 10% of Internet-sold breast milk tested contained bovine milk, which is not recommended at all for infants under six months—the primary group for whom human milk is intended.

By prohibiting the direct sale of human milk over the Internet, those who wish to provide (that is sell) their extra milk or donate their milk can go through established, evidenced-based channels that test for the safety of the milk and ensure that human milk gets to human infants. Support for a strong milk banking system will ultimately promote and protect breastfeeding and allow us to achieve equitable access to human milk as a right afforded to everyone as well as insurance towards successful breast milk feeding for every mother and baby and vice versa. Further, just four years ago, in an article in *Public Health Report*, David Stephanie Dawson, JD MPH wrote:

> As the informal sale of human milk continues to grow, lawmakers should consider adopting specific regulations governing the sale, processing, and shipment of human milk, particularly with regard to impersonal and informal Internet sales, to better ensure the health and safety of children in these potentially dangerous transactions.[xii]

The need is here, and the time is now.

Combined, HB 4206 and HB 4691 have the potential to place Michigan at the forefront of an emergent area of public health policy that is essential to the health and well-being of infants and mothers, as well as overall community health in the state of Michigan. I hope to have your support on these bills, and I welcome any questions that the committee may have before handing testimony off to Kendra Rowser of the Black Mothers Breast Feeding Association and to Cindy Duff of the Mothers Milk Bank at Bronson Methodist Hospital in Kalamazoo.

End Notes:

[i] View https://www.cia.gov/library/publications/the-world-factbook/rankorder/2091rank.html for data points on infant mortality rate by country and www.cdc.gov/reproductivehealth/MaternalInfantHealth/InfantMortality.htm for additional comprehensive list of topics and data from the Centers for Disease Control.

[ii] "EXECUTIVE SUMMARY: Breastfeeding and the Use of Human Milk," in *Pediatrics* Volume 129, Number 3, March 2012 p. 601-03. Available at www.pediatrics.org/cgi/doi/10.1542/peds.2011-3553doi:10.1542/peds.2011-3553

[iii] Gephart, Shiela M., RN BSN et al. "Necrotizing Enterocolitis Risk: State of the Science" in Adv Neonatal Care. 2012 Apr; 12(2): 77–89. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357630/
The authors cite the following studies in the passage indicated:
1. Caplan MS. Neonatal necrotizing enterocolitis [Introduction] Semin Perinatol. 2008;32(2):69. [PubMed]
2. Neu J, Mshvildadze M, Mai V. A roadmap for understanding and preventing necrotizing enterocolitis. Curr Gastroenterol Rep. 2008;10(5):450–457. [PubMed]
3. Luig M, Lui K. NSW ACT NICUS Group. Epidemiology of necrotizing enterocolitis—part II: risks and susceptibility of premature infants during the surfactant era: a regional study. J Paediatr Child Health. 2005;41(4):174–179. [PubMed]

[iv] See ii.

[v] Good, M., Sodhi, C.P., Egan, C.E. *et al.* "Breast milk protects against the development of necrotizing enterocolitis through inhibition of Toll-like receptor 4 in the intestinal epithelium via activation of the epidermal growth factor receptor." In *Mucosal Immunol.* 2015 Sep;8(5):1166-79. doi: 10.1038/mi.2015.30. Epub 2015 Apr 22. (See http://www.ncbi.nlm.nih.gov/pubmed/25899687 for abstract.)

[vi] See ii.

[vii] See iii. The authors cite the following study: 9. Bisquera JA, Cooper TR, Berseth CL. Impact of necrotizing enterocolitis on length of stay and hospital charges in very low birth weight infants. Pediatrics. 2002;109(3): 423–428. [PubMed]

[viii] Ganapathy, V., Joel W. Hay, and Jae H. Kim. "Costs of Necrotizing Enterocolitis and Cost-Effectiveness of Exclusively Human Milk-Based Products in Feeding Extremely Premature Infants," in *Breastfeeding Medicine*, Volume 6, Number 0, 2011. Available at http://www.pqcnc.org/documents/milkwelldoc/ValueOfHumanMilkInNICU.pdf

[ix] The summary of Action 12 of the Surgeon General's Call to Action to Support Breast Feeding is "Identify and address obstacles to greater availability of safe banked donor milk for fragile infants. Growing evidence supports the role of donated human milk in assisting infants with special needs, such as infants in newborn intensive care units who are unable to receive their own mothers' milk, to achieve the best possible health outcome. In these situations, use of banked donor milk may protect the infant from the risks that might result from not breastfeeding. Unfortunately, demand for donor milk outpaces supply because of logistical challenges related to transportation of donated milk, the lack of clarity in oversight, and the high cost of providing banked human milk. A national strategy is needed to efficiently and effectively address the issues involved in providing banked donor milk to vulnerable infant populations. See http://www.surgeongeneral.gov/library/calls/breastfeeding/calltoactiontosupportbreastfeeding.pdf) for the full text of the U.S. Surgeon General's 2011 Call to Action to Support Breastfeeding.

[x] Sarah A. Keim et al., "Microbial Contamination of Human Milk Purchased Via the Internet" in PEDIATRICS Volume 132, Number 5, November 2013, pp. 1227-1237. Available at http://m.pediatrics.aappublications.org/content/early/2013/10/16/peds.2013-1687.full.pdf

[xi] Sarah A. Keim et al., "Cow's Milk Contamination of Human Milk Purchased via the Internet" in PEDIATRICS Volume 135, number 5, May 2015, pp. 1-6. Available at http://m.pediatrics.aappublications.org/content/early/2015/03/31/peds.2014-3554.full.pdf

[xii] David Stephanie Dawson, JD, MPH. "Legal Commentary on the Internet Sale of Human Milk" in Public Health Report. 2011 Mar-Apr; 126(2): 165–166. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3056027/

Additional Resources:

Centers for Disease Control 2014 Breastfeeding Report Card:
http://www.cdc.gov/breastfeeding/pdf/2014breastfeedingreportcard.pdf

March of Dimes: Preterm birthrate data:
http://www.marchofdimes.org/Peristats/ViewSubtopic.aspx?reg=99&top=3&stop=55&lev=1&slev=1&obj=3

March of Dimes: Premature Birth Report Card for Michigan
http://www.marchofdimes.org/peristats/pdflib/998/premature-birth-report-card-Michigan.pdf

Michigan Child Health Policy Briefs "Children's Health Issues in Michigan-Infant Mortality"
http://www.childhealthfactsmichigan.org/?page_id=44

Michigan Department of Health & Human Services Breastfeeding Rate and Duration Report
http://www.michigan.gov/documents/mdch/BF_Rate_and_Duration_Summary_Final_03202015_489074_7.pdf

Michigan League for Public Policy Kids Count Report 2014 Visit http://datacenter.kidscount.org

Organisation for Economic Cooperation and Development (OECD) http://www.oecd.org World Health Organization "Born to Soon" Report: http://www.who.int/pmnch/media/news/2012/201204_borntoosoon_countryranking.pdf